

**REMARKS****Interview Summary**

Applicants' Agent, Jesse Fecker, would like to thank the Examiner for conducting the telephonic interview of April 21, 2004, and for her helpful comments. During the interview the enablement rejection of record was discussed.

The Examiner indicated that it was the position of the U.S. Patent and Trademark Office that terms such as "prevent" and "prophylaxis" indicated complete (100%) inhibition of the onset of a condition. Because of the extreme position taken by the U.S.P.T.O., Applicants' Agent tentatively agreed to use alternate language in the claims, such as substituting the term "inhibit".

**Claim Amendments**

Claim 4 has been amended to replace the term "prophylactically" with the phrase "to inhibit the onset of mucositis". Support for this amendment can be found on page 5 lines 28-29. Claim 32 has been amended to correct a typographical error. No new matter has been added.

**Rejection of Claim 4 Under 35 U.S.C § 112, First Paragraph**

Claim 4 is rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. The Examiner states that while the specification is enabling for the inhibition of mucositis and the reduction in severity and size of mucositis, it does not reasonably provide enablement for the prophylaxis and/or prevention of mucositis. The Examiner further states that in order to overcome the enablement rejection, Applicants must provide data showing 100% prevention in 100% of the persons identified with the risk factor 100% of the time and for the life of the person having the risk factor.

It is the position of the U.S. Patent and Trademark Office that terms such as "prevent" and "prophylaxis" indicate complete (100%) inhibition of the onset of a condition in 100% of cases, whereas the term "inhibit" encompasses everything less than 100%. Applicants disagree with U.S. Patent and Trademark Office on this matter, as one skilled in the art knows that even therapies approved by the F.D.A. which are used prophylactically to prevent diseases do not show 100% prevention in 100% of the persons identified with the risk factor for the life of the

person having the risk factor. As such, the Office's interpretation of "prevent" and "prophylaxis" is unrealistic.

To overcome this rejection, Claim 4 has been amended to substitute the term "prophylactically" with the phrase "to inhibit the onset of mucositis". It is to be understood that 100% inhibition in 100% of the cases was not contemplated by the use of the term "prophylactically" and therefore no narrowing of the claim has occurred. The amendment simply further clarifies the subject matter encompassed by the claim.

"Inhibit" is understood to mean that as a preventative therapy, ionene polymers reduce the number of patients who develop mucositis and/or reduce the severity of the mucositis that develops. Claim 4, as amended, further clarifies that 100% prevention of mucositis in 100% of the persons identified to be at risk for mucositis 100% of the time and for the life of the person being at risk, is not contemplated by the claim. This amendment should not be construed to mean that the claimed method is deficient in any way.

Thus, Claim 4, as amended, is enabled and meets the requirements of 35 U.S.C. §112, First Paragraph. Reconsideration and withdrawal of the rejection are respectfully requested.

#### Withdrawn Claims

Claims 9, 11-19 and 25-32, are withdrawn from consideration by the Examiner as being drawn to a non-elected species. Claims 9 and 11-19 are dependent on Claim 1, and therefore should be examined upon allowance of Claim 1, which serves as a bridging claim. Rejoinder of Claims 9 and 11-19 is respectfully requested upon allowance of Claim 1.

Claims 25-32 are directed to methods of treating mucositis in a mammal, comprising administering to said mammal an effective amount of a particular ionene polymer. Claims 25-32 could therefore be amended to be properly dependent from Claim 1. Examination of Claims 25-32 is respectfully requested upon allowance of Claim 1.

#### Provisional Rejection of Claims 1-8, 10 and 20-44 Under Obviousness-Type Double Patenting

Claims 1-8, 10 and 20-44 are provisionally rejected under obvious-type double patenting over Claims 36-50 of co-pending U.S. Patent Application No. 10/051,765. In order to obviate the rejection, Applicants are concurrently filing a Terminal Disclaimer in compliance with 37

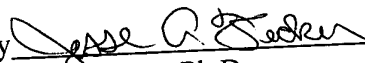
C.F.R. § 1.321(c) in which the owner of 100 percent interest in the instant application, Genzyme Corporation, thereby disclaims the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of U.S. Patent Application No. 10/051,765.

### CONCLUSION

In view of the above amendments, remarks, and concurrent filing of a Terminal Disclaimer, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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